indge Bernian

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK



CV 00035

MERCK EPROVA AG and MERCK KGaA

07 CV

Plaintiffs,

-vs.-

PROTHERA, INC.,

Defendant.

JURY DEMAND

COMPLAINT E

JAN 03 2008

Plaintiffs Merck Eprova AG ("Merck Eprova") and Merck KGaA (collectively "Merck" or "Plaintiffs") file this Complaint against Defendant ProThera, Inc. ("ProThera" or "Defendant") and in support thereof alleges as follows:

NATURE AND BASIS OF ACTION

1. This action arises out of Defendant's knowing and willful false and misleading labeling of its product. Defendant's actions constitute false advertising in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B); contributory false advertising in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B); contributory federal trademark infringement in violation of Section 32(1) of the Lanham Act, 15 U.S.C. § 1114(1); trademark dilution in violation of Section 43(c) of the Federal Dilution Act of 1995, 15 U.S.C. § 1125(c); federal unfair competition in violation of Section 43(a)(1)(A) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(A); unfair competition in violation of New York common law; trademark dilution in violation of N.Y. Gen. Bus. Law § 360(l); deceptive trade practices in violation of N.Y. Gen. Bus. Law § 349(h); and false advertising in violation of N.Y. Gen.

Bus. Law § 350(e)(3). Merck seeks temporary, preliminary and permanent injunctive relief, actual damages, punitive damages, and recovery of Merck's costs and reasonable attorneys' fees incurred in connection with this action.

THE PARTIES

- 2. Merck Eprova is a Swiss corporation with a principal place of business at Im Laternenacker 5, CH-8200 Schaffhausen, Switzerland. Merck KGaA, Darmstadt, is a German association by limited shares, with a principal place of business at Frankfurter Str. 250, D-64293 Darmstadt, Germany.
- 3. Upon information and belief, ProThera is a Nevada Corporation with its principal place of business at 10439 Double R Blvd., Reno, Nevada 89521.

JURISDICTION AND VENUE

- 4. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338 because this case arises under the Lanham Act, 15 U.S.C. §§ 1051, et seq.
- 5. This Court has jurisdiction over Merck's state law claims pursuant to 28 U.S.C. § 1367 and the doctrine of supplemental jurisdiction.
- 6. This Court has personal jurisdiction over the Defendant because the Defendant transacts business within the State of New York, contracts to supply goods or services in the State of New York, and has engaged in tortious acts within the State of New York.
- 7. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b) because a substantial part of the events and injury giving rise to Merck's claims have and continue to occur in this district.

FACTUAL BACKGROUND

A. Merck, Its Product L-5-MTHF and Its Famous Trademark, METAFOLIN

- 8. Merck Eprova is the Swiss affiliate of Merck KGaA and provides active pharmaceutical and dietary ingredients to the pharmaceutical and nutritional industry for use in clinical trials and commercial product applications. One such product is marketed in connection with famous and distinctive trademarks consisting in whole or in part of the term METAFOLIN (the "METAFOLIN Marks").
- 9. The METAFOLIN Marks have been used by Merck and its customers in connection with the dietary ingredient N-[4-[[(2-amino-5,6,7,8-tetrahydro-4-hydroxy-5methyl-(6S)-pteridinyl)methyl]amino]benzoyl]-L-glutamic acid, calcium salt, called L-5-methyltetrahydrofolic acid, calcium salt ("L-5-MTHF"), which is a pure diastereoisomeric form of the compound 5-methyltetrahydrofolic acid.
- Merck filed a New Dietary Ingredient Notification with the United States 10. Food and Drug Administration ("FDA") in 2001 for its dietary ingredient L-5-MTHF for use in dietary supplements. L-5-MTHF is a source of folate, an essential human vitamin of the B complex.
- For over 5 years, Merck's dietary ingredient L-5-MTHF has been used in dietary supplements, including, pregnancy vitamins, medical foods, nutritional supplements, and food for special dietary use.
- 12. The METAFOLIN Marks are owned by Merck KGaA. Merck Eprova has an exclusive license from Merck KGaA to use these METAFOLIN Marks in the United States. Merck KGaA owns U.S. Trademark Registration Nos. 3001087 and 2526532 for the METAFOLIN Marks. True and correct copies of these Trademark Registrations are attached as Exhibit A.

- 13. Merck began manufacturing and distributing its L-5-MTHF dietary ingredient in 2002. Since then, Merck and its customers have established a considerable market in the United States for the product. Merck receives substantial revenue from its L-5-MTHF dietary ingredient.
- 14. Merck is the sole importer, licensor, and primary distributor of the bulk substance L-5-MTHF in the United States, directly and through its licensees. Merck's customers use METAFOLIN brand L-5-MTHF in various dietary supplements, medical foods, nutritional supplements, pregnancy vitamins, and food for special dietary use. The presence of genuine L-5-MTHF is used by Merck's customers as a unique selling point. Merck licenses the use of the trademark METAFOLIN to its customers who buy Merck's brand of L-5-MTHF.
- 15. Merck has conducted extensive clinical and laboratory trials and testing on its L-5-MTHF.
- 16. The unique benefits of L-5-MTHF come from the fact that it consists of a single diastereoisomer of the compound 5-methyltetrahydrofolic acid and the fact that it is a stable crystalline product.
- 17. Many products, such as 5-methyltetrahydrofolic acid, occur as mixtures of two or more diastereoisomers if chemically synthesized.
- 18. The various diastereoisomers that are present in such mixtures can have radically different properties from one another. In some cases, one diastereoisomer can have a therapeutic effect, while another diastereoisomer is therapeutically ineffective. In the most severe instances, one diastereoisomer may be highly toxic while another diastereoisomer may have enhanced pharmacological utility. Thus, there are often great

benefits to providing patients and consumers with a product that contains only a single diastereoisomer as opposed to a diastereoisomeric mixture.

- 19. Diastereoisomers are distinguished from one another through naming conventions that reflect their different properties. One such naming convention uses a "D" in the name of the compound for one diastereoisomer and an "L" in the name of the compound to indicate a different diastereoisomer.
- 20. The product 5-methyltetrahydrofolic acid is a mixture of two diastereoisomers, the "L-form" and the "D-form."
- 21. The L-form of folate (i.e., L-5-MTHF) is highly preferable to the D-form (i.e., D-5-MTHF) because the L-form is the naturally occurring predominant form of folate found in food and the human body. The L-form is the biologically active form of folate and has proven to have a high degree of bioavailability (the rate at which a drug or other substance is available at the targeted place in the body) in humans. In contrast, the D-form is an unnatural form of folate, which humans are unable to metabolize.
- 22. L-5-MTHF is the pure diastereoisomeric form of folate used by cells in the body. In humans, this particular compound is the predominant form in circulation and transport into the tissues, and it is the only folate that can cross the blood-brain barrier.
- 23. In fact, because the D-form exhibits virtually no beneficial activity, the presence of any of the D-5-MTHF diastereoisomer could compete with the uptake and activity of the L-5-MTHF diastereoisomer and, therefore, could reduce the overall usability of the compound.
- 24. Merck's L-5-MTHF complies with all applicable requirements for dietary ingredients established by the FDA.

- 25. Over the years, Merck has spent many millions of dollars researching and developing its L-5-MTHF, and devotes significant financial resources each year to marketing its product.
- Merck is acclaimed worldwide for its novel drugs and therapeutic 26. products.
- Merck's products are some of the most well-known and well-respected 27. medical and dietetic products worldwide.
- Over the years, Merck has worked hard to expand and to build its trade 28. name, trademarks, and products.
- Merck has over the years worked extremely hard to ensure that the quality 29. of the Merck product L-5-MTHF is extraordinarily high and that this product is of the highest safety and efficacy.
- For example, Merck conducted countless experiments and tests to 30. determine the safety and efficacy of its L-5-MTHF, and spent years and millions of dollars on research and development of this product.

В. **Defendant's Unlawful Conduct**

- Defendant is in no way affiliated with Merck or its related entities. 31.
- Upon information and belief, Defendant is a manufacturer, distributor and 32. supplier of nutritional dietary ingredients.
- ProThera sells and distributes its products worldwide, including sale and 33. distribution in the United States and in New York State, in particular.

- 34. ProThera sells dietary supplements containing the dietary ingredient 5-MTHF (the "ProThera Compound"), the diastereoisomeric mixture, which it has falsely labeled, and continues to falsely label, as containing the pure L-5-MTHF diastereoisomer.
- 35. That ProThera mislabels its product by using the L-5-MTHF label is readily apparent because ProThera fails to follow standard labeling language that has been approved by the FDA. Specifically, the FDA issued a New Dietary Ingredient Notification ("NDI") for another company seeking to use and market 5-MTHF, the identical ingredient contained in the ProThera Compound. The NDI stated that the requesting company must label its product as "methyltetrahydrofolate" or "5-MTHF." Thus, the FDA ruling establishes that it is improper to label ProThera's product, which contains 5-MTHF as containing pure L-5-MTHF.
- 36. ProThera was previously a customer of Merck. Beginning in August 2005, Merck supplied L-5-MTHF to ProThera and permitted ProThera to use the METAFOLIN Marks pursuant to a Supply and License Agreement ("the License Agreement").
- 37. Merck provided ProThera with notice of termination of the License Agreement on March 14, 2006, and termination was effective August 14, 2006.
- 38. Merck gave ProThera additional time to deplete its inventory. Upon Merck's agreement to accept back one kilogram of METAFOLIN, ProThera indicated that its inventory should be depleted by September 2006.
- 39. As such, neither ProThera, nor its customers, were authorized to continue to sell product containing METAFOLIN or to use the METAFOLIN Marks beyond September 2006.

- 40. In early 2007, Merck tested various products manufactured and/or distributed by ProThera. Analytical tests confirmed that those ProThera products claiming to contain L-5-MTHF did not contain the pure diastereoisomeric form indicated on the label or advertising material, but instead such products contained the diastereoisomeric mixture 5-MTHF. Moreover, Merck learned that ProThera and some of its distributors were still using the METAFOLIN Marks despite the termination of the License Agreement and the expiration of the sell-off period.
- 41. On February 14, 2007, Merck sent ProThera an email demanding that it cease infringing the METAFOLIN Marks and falsely advertising the composition of its products. Despite repeated efforts to get ProThera to comply with this demand, ProThera's unlawful activities continued.
- 42. ProThera's distributors continued to infringe the METAFOLIN Marks. Merck sent a cease and desist letter to ProThera on October 8, 2007 noting that at least two distributors, Prescription 2000 and Triune Wellness, continued to infringe the METAFOLIN Marks. Indeed, on the labels of two Triune Wellness products purchased in the summer of 2007, in particular the Multiple Vitamin and Mineral Trace Element Supplement (without iron) and Longevity & Wellness Essentials for Women (without iron), the METAFOLIN Marks were used. Upon information and belief, Triune Wellness continues to infringe these marks.
- 43. Product labels and advertising materials provided to the public by ProThera falsely claim that the ProThera Compound has pure L-5-MTHF when, in fact, it does not.

- 44. ProThera has knowledge that the ProThera Compound is the diastereoisomeric mixture 5-MTHF and not the pure L-5-MTHF diastereoisomer.
- 45. In fact, in correspondence dated March 29, 2007 ProThera admitted that the ProThera Compound is not "chirally pure, but is a racemic mixture of the two optical isomers," i.e., a diastereoisomeric mixture of 5-MTHF containing both L-5-MTHF and D-5-MTHF.
- 46. Despite this admission, ProThera continues to falsely represent to the consuming public that the ProThera Compound contains the pure L-5-MTHF diastereoisomer.
- 47. Upon information and belief, through materials accessible through the internet and through materials distributed to customers and potential customers, ProThera has marketed the Prothera Compound that contains the diastereoisomeric mixture 5-MTHF as containing the pure L-5-MTHF diastereoisomer in an effort to induce customers to believe that the ProThera Compound contains genuine L-5-MTHF, when it does not.
- 48. ProThera has performed the aforementioned acts globally, as well as within the United States and the State of New York.
- 49. ProThera is deliberately misrepresenting to consumers, the public and the marketplace that the ProThera Compound has the same efficacy and safety as Merck's proprietary L-5-MTHF, when, in fact, the two products are not the same and do not have the same therapeutic effect.

- 50. Moreover, ProThera's customers through product labels and/or material available on their websites falsely advertise that the ProThera Compound contains pure L-5-MTHF.
- 51. Upon information and belief, ProThera knew that its customers were improperly labeling the ProThera Compound as containing pure L-5-MTHF and allowed and encouraged the customers to label the ProThera Compound as containing pure L-5-MTHF, despite it containing the diastereoisomeric mixture 5-MTHF.
- 52. ProThera has advertised that the ProThera Compound contains a pure diastereoisomer of the highest quality, when, in fact, it does not.
- 53. The ProThera Compound is marketed as a competing product to products containing genuine L-5-MTHF.
- 54. The public's use of the ProThera Compound will have inferior therapeutic results as compared to products containing pure L-5-MTHF because the biologically inactive D-diastereoisomer could compete with the uptake and activity of the L-diastereoisomer. This will cause consumers to doubt the overall efficacy of all products containing pure L-5-MTHF.
- 55. Any of the above results could expose the general public, including consumers in the United States and New York, to dangerous medical implications.
- 56. The distribution and sale of the ProThera Compound has and will continue to cause Merck to lose sales of its genuine L-5-MTHF to both existing Merck customers and to potential customers.
- 57. The marketing of the ProThera Compound as containing genuine L-5-MTHF is likely to tarnish the reputation of both Merck and its L-5-MTHF in that the

ProThera Compound fails to provide the expected level of purity and is inferior to L-5-MTHF and products containing pure L-5-MTHF.

COUNT I

FALSE ADVERTISING IN VIOLATION OF SECTION 43(a)(1)(B) OF THE LANHAM ACT, 15 U.S.C. § 1125(a)(1)(B)

- 58. Merck incorporates herein and realleges, as if fully set forth in this Paragraph, the allegations of Paragraphs 1 through 57 above, inclusive.
- 59. Defendant's statements made on the internet, advertising and promotions, and labeling of the ProThera Compound, which state that the ProThera Compound contains the pure L-5-MTHF diastereoisomer, are materially false statements that misrepresent the nature, characteristics and qualities of the ProThera Compound. These are material misrepresentations upon which customers or potential customers have, and will rely. Defendant's actions therefore mislead and harm customers and consumers as well as damage Merck's sales, good name and reputation in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).
- 60. Given ProThera's knowledge and admission that the ProThera Compound contains the diastereoisomeric mixture 5-MTHF, and not the pure L-5-MTHF diastereoisomer, the aforesaid acts were undertaken willfully and deliberately and with the intention of causing confusion, mistake, or deception.
- 61. The aforesaid acts of Defendant have caused, and will continue to cause, damage to Plaintiffs in an amount to be determined at trial.
- 62. The aforesaid acts of Defendant have caused, and unless restrained and enjoined by this Court, will continue to cause irreparable harm, loss, and injury to Plaintiffs for which Plaintiffs have no adequate remedy at law.

COUNT II

CONTRIBUTORY FALSE ADVERTISING IN VIOLATION OF SECTION 43(a)(1)(B) OF THE LANHAM ACT, 15 U.S.C. § 1125(a)(1)(B)

- 63. Merck incorporates herein and realleges, as if fully set forth in this Paragraph, the allegations of Paragraphs 1 through 62 above, inclusive.
- 64. Upon information and belief, Defendant has falsely told its distributors that the ProThera Compound contains the pure L-5-MTHF diastereoisomer.
- 65. Defendant induced its distributors to engage in false advertising by labeling and marketing the ProThera Compound as containing the pure L-5-MTHF diastereoisomer.
- 66. Defendant knew or had reason to know that its distributors would engage in false advertising by labeling and marketing the ProThera Compound as containing the pure L-5-MTHF diastereoisomer.
- As a result, ProThera's distributors made materially false statements that misrepresent the nature, characteristics and qualities of the ProThera Compound. These are material misrepresentations upon which customers or potential customers have and will rely. Defendant's actions, therefore, caused its distributors to mislead and harm customers and consumers as well as damage Merck's sales, good name and reputation in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).
- 68. Given ProThera's knowledge and admission that the ProThera Compound contains the diastereoisomeric mixture 5-MTHF and not the pure L-5-MTHF diastereoisomer, the aforesaid acts were undertaken willfully and deliberately and with the intention of causing confusion, mistake, or deception.

- 69. The aforesaid acts of Defendant have caused, and will continue to cause, damage to Plaintiffs in an amount to be determined at trial.
- 70. The aforesaid acts of Defendant have caused, and unless restrained and enjoined by this Court, will continue to cause irreparable harm, loss, and injury to Plaintiffs for which Plaintiffs have no adequate remedy at law.

COUNT III

CONTRIBUTORY FEDERAL TRADEMARK INFRINGEMENT IN VIOLATION OF SECTION 32(1) OF THE LANHAM ACT, 15 U.S.C. § 1114(1)

- 71. Merck incorporates herein and realleges, as if fully set forth in this Paragraph, the allegations of Paragraphs 1 through 70 above, inclusive.
- 72. The use of the METAFOLIN Marks by ProThera's customer(s) in connection with the ProThera Compound, is likely to confuse, mislead, or deceive the public as to the source or origin of the ProThera Compound. ProThera's customer(s)' unauthorized use of the METAFOLIN Mark infringes Merck's exclusive rights in its federally registered trademarks, in violation of Section 32(1) of the Lanham Act, 15 U.S.C. § 1114(1). ProThera's knowledge and encouragement of its customer(s) to use the federally registered METAFOLIN Mark without Merck's consent, in connection with the ProThera Compound is contributory infringement in violation Section § 32(1) of the Lanham Act, 15 U.S.C. § 1114(1).
- 73. ProThera's customer(s)' unauthorized use of the METAFOLIN Marks have enabled and will continue to enable, ProThera to earn profits to which it is not in equity or good conscience entitled and has unjustly enriched ProThera at Merck's expense, all to ProThera's profit and Merck's damage.

- 74. The aforesaid acts were undertaken willfully and deliberately.
- 75. The aforesaid acts of Defendant have caused, and will continue to cause, damage to Plaintiffs in an amount to be determined at trial.
- 76. The aforesaid acts of Defendant have caused, and unless restrained and enjoined by this Court, will continue to cause irreparable harm, loss, and injury to Plaintiffs for which Plaintiffs have no adequate remedy at law.

COUNT IV

FEDERAL TRADEMARK DILUTION IN VIOLATION OF SECTION 43(c) OF THE FEDERAL DILUTION ACT OF 1995, 15 U.S.C. § 1125(a)

- 77. Merck incorporates herein and realleges, as if fully set forth in this Paragraph, the allegations of Paragraphs 1 through 76 above, inclusive.
- 78. As a result of Merck's long term and widespread use of its METAFOLIN Marks and the amount of publicity surrounding its dietary supplement, Merck's METAFOLIN Marks have achieved a level of recognition such that they are famous marks and have been famous marks prior to the acts of ProThera complained of herein.
- 79. ProThera's tolerance and encouragement of its customer(s)' unauthorized use of the METAFOLIN Marks in connection with its website, other advertising, labeling and marketing outlets in connection with the ProThera Compound, has diluted and tarnished the distinctive quality of Merck's famous METAFOLIN Marks in violation of the Federal Dilution Act of 1995, 15 U.S.C. § 1125(c).
- 80. ProThera's tolerance and encouragement of its customer(s)' unauthorized use of the METAFOLIN Marks was willful and intended to trade off of Merck's reputation and goodwill. Additionally, the METAFOLIN Marks are used in conjunction with an inferior product for which such use was willful and intended to trade off of

Merck's reputation and goodwill. As such, ProThera's customer(s)' unauthorized use of the METAFOLIN Mark has enabled, and will continue to enable ProThera to earn profits to which it is not in equity or good conscience entitled and has unjustly enriched ProThera at Merck's expense, all to ProThera's profit and Merck's damage.

- 81. The aforesaid acts were undertaken willfully and deliberately.
- 82. The aforesaid acts of Defendant have caused, and will continue to cause, damage to Plaintiffs in an amount to be determined at trial.
- 83. The aforesaid acts of Defendant have caused, and unless restrained and enjoined by this Court, will continue to cause irreparable harm, loss, and injury to Plaintiffs for which Plaintiffs have no adequate remedy at law.

COUNT V

FEDERAL UNFAIR COMPETITION IN VIOLATION OF SECTION 43(a)(1)(A) OF THE LANHAM ACT, 15 U.S.C. § 1125(a)(1)(A)

- 84. Merck incorporates herein and realleges, as if fully set forth in this Paragraph, the allegations of Paragraphs 1 through 83 above, inclusive.
- 85. Defendant's statements made on the internet, advertising and promotions, and labeling of the ProThera compound, which state that the ProThera Compound contains the pure L-5-MTHF diastereoisomer, are materially false statements.
- 86. Such materially false statements have caused and are likely to continue to cause consumer confusion, mistake, or deception as to the origin, sponsorship or approval of the ProThera Compound.
- 87. ProThera, therefore, has willfully promoted the ProThera Compound in interstate commerce so as to cause confusion or mistake among the public as to the

origin, sponsorship or approval of the ProThera Compound, all to ProThera's profit and the public's and Merck's damage.

- 88. Given ProThera's knowledge and admission that the ProThera Compound contains the diastereoisomeric mixture 5-MTHF and not the pure L-5-MTHF diastereoisomer, and that the product being distributed does not contain genuine METAFOLIN, the aforesaid acts were undertaken willfully and deliberately.
- 89. The aforesaid acts of ProThera constitute use of false descriptions and false representations in interstate commerce in violation of § 43(a)(1)(A) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(A).
- 90. The aforesaid acts of ProThera have caused, and will continue to cause, damage to Plaintiffs in an amount to be determined at trial.
- 91. The aforesaid acts of Defendant have caused, and unless restrained and enjoined by this Court, will continue to cause irreparable harm, loss, and injury to Plaintiffs for which Plaintiffs have no adequate remedy at law.

COUNT VI

COMMON LAW UNFAIR COMPETITION

- 92. Merck incorporates herein and realleges, as if fully set forth in this Paragraph, the allegations of Paragraphs 1 through 91 above, inclusive.
- 93. ProThera has made false statements to the public and its customers and has mislabeled the ProThera Compound with the intent of deceiving and misleading the public as to the quality and nature of its product.
- 94. The aforesaid acts have enabled ProThera to misappropriate the labors and expenditures of Merck in developing the market for the pure L-5-MTHF diastereoisomer.

- 95. Additionally, the aforesaid acts have caused, and are likely to continue to cause injury to the public and to Merck's sales, business reputation, and result in ProThera unfairly competing with Merck.
- 96. Given ProThera's knowledge and admission that the ProThera Compound contains the diastereoisomeric mixture 5-MTHF and not the pure L-5-MTHF diastereoisomer, the aforesaid acts were undertaken willfully and deliberately.
- 97. The aforesaid acts of Defendant have caused, and will continue to cause, damage to Plaintiffs in an amount to be determined at trial.
- 98. The aforesaid acts of Defendant have caused, and unless restrained and enjoined by this Court, will continue to cause irreparable harm, loss, and injury to Plaintiffs for which Plaintiffs has no adequate remedy at law.

COUNT VII

TRADEMARK DILUTION IN VIOLATION OF N.Y. GEN. BUS. LAW § 360(1)

- 99. Merck incorporates herein and realleges, as if fully set forth in this Paragraph, the allegations of Paragraphs 1 through 98 above, inclusive.
- 100. The METAFOLIN Marks are highly distinctive and achieved this distinctiveness before ProThera commenced using them.
- 101. ProThera's customer(s)' unauthorized use of the METAFOLIN Marks and improper and materially false labeling of its ProThera Compound has caused injury to Merck's sales and business reputation, and has diluted the distinctive quality of the METAFOLIN Marks in violation of N.Y. Gen. Bus. Law § 360(1).

- 102. ProThera's acts have caused, and unless restrained by this Court, will continue to cause, great and irreparable damage to Merck's business and goodwill for which Merck has no adequate remedy at law.
- 103. As a result of ProThera's willful and intentional misconduct, Merck is therefore entitled to appropriate relief as prayed for hereinafter, including preliminary and permanent injunctive relief.
- 104. As a result of ProThera's willful and intentional misconduct, Merck is also entitled to recover monetary damages permitted by statute from ProThera, in an amount to be determined at trial.

COUNT VIII

<u>DECEPTIVE TRADE PRACTICES</u> <u>IN VIOLATION OF N.Y. GEN. BUS. LAW § 349(h)</u>

- 105. Merck incorporates herein and realleges, as if fully set forth in this Paragraph, the allegations of Paragraphs 1 through 104 above, inclusive.
- New York against Merck and the public in the conduct of its business through the following consumer-oriented acts: making false and misleading statements on the internet; making false and misleading commercial advertising or promotions; and mislabeling the ProThera Compound as containing the pure L-5-MTHF diastereoisomer, all of which materially misrepresent the nature, characteristics and qualities of the goods and services associated with the ProThera Compound. The aforesaid acts of ProThera are in violation of N.Y. Gen. Bus. Law § 349(h).

- 107. The aforesaid misleading acts of ProThera have additionally caused, and are likely to continue to cause injury to the public, including consumers in New York, and injury to Merck's sales and business reputation.
- 108. ProThera's acts have caused, and unless restrained by this Court, will continue to cause, great and irreparable damage to the public and to Merck's business and goodwill for which Merck and the public have no adequate remedy at law.
- 109. As a result of ProThera's willful and intentional misconduct, Merck and the public are therefore entitled to appropriate relief as prayed for hereinafter, including preliminary and permanent injunctive relief.
- 110. Moreover, ProThera willful and knowing violation of Section 349(h) warrants treble damages and the recovery of attorneys' fees.

COUNT IX

FALSE ADVERTISING IN VIOLATION OF N.Y. GEN. BUS. LAW § 350(e)(3)

- 111. Merck incorporates herein and realleges, as if fully set forth in this Paragraph, the allegations of Paragraphs 1 through 110 above, inclusive.
- against Merck and the public in the conduct of its business through the following consumer-oriented acts: making false and misleading statements on the internet; making false and misleading commercial advertising or promotions; and mislabeling the ProThera Compound as containing the pure L-5-MTHF diastereoisomer, all of which materially misrepresent the nature, characteristics and qualities of the goods and services associated with the ProThera Compound. The aforesaid acts of ProThera are in violation of N.Y. Gen. Bus. Law § 350(e)(3).

- 113. The aforesaid false statements of ProThera have additionally caused, and are likely to continue to cause injury to the public, including consumers in New York, and injury to Merck's business representation.
- 114. ProThera's acts have caused, and unless restrained by this Court, will continue to cause, great and irreparable damage to the public and to Merck's business and goodwill for which Merck and the public have no adequate remedy at law.
- 115. As a result of ProThera's willful and intentional misconduct, Merck and the public are therefore entitled to appropriate relief as prayed for hereinafter, including preliminary and permanent injunctive relief.
- 116. Moreover, ProThera's willful and knowing violation of Section 350(e)(3) warrants treble damages and the recovery of attorneys' fees.

JURY DEMAND

MERCK demands a trial by jury of all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Merck respectfully prays for the following relief:

A. The Court enter judgment that Defendant, as a result of its willful, deliberate, and materially false statements regarding the quality and content of its product has engaged in: false advertising in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B); contributory false advertising in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B); contributory federal trademark infringement in violation of 32(l) of the Lanham Act, 15 U.S.C. § 1114(l); trademark dilution in violation of Section 43(c) of the Federal Dilution Act of 1995, 15 U.S.C. § 1125(c); federal unfair competition in violation of Section 43(a)(1)(A) of the

Lanham Act, 15 U.S.C. § 1125(a)(1)(A); unfair competition in violation of New York common law; trademark dilution in violation of N.Y. Gen. Bus. Law § 360(1); deceptive trade practices in violation of N.Y. Gen. Bus. Law § 349(h); and false advertising in violation of N.Y. Gen. Bus. Law § 350(e)(3).

- В. The Court enter judgment finding that this is an exceptional case:
- C. The Court issue temporary, preliminary, and permanent injunctions ordering Defendant to, inter alia, immediately cease all distribution and sale of the ProThera Compound and any other product that contains 5-MTHF or L-5-MTHF;
- D. The Court order a recall of all of the ProThera Compound currently in the marketplace;
- E. The Court order a recall of all products containing the ProThera Compound currently in the marketplace;
- F. The Court order that ProThera engage in a program of corrective advertising, satisfactory to Merck, to ameliorate the false and misleading information that ProThera has promulgated;
- G. The Court grant an award of damages in an amount sufficient to compensate Merck for injury it has sustained as a consequence of Defendant's unlawful acts;
 - H. The Court grant an award of treble damages;
- I. The Court grant an award of punitive damages in an amount sufficient to punish and deter Defendant from engaging in further knowing acts of unfair competition;
- J. The Court grant the costs of this action and the reasonable attorneys' fees Merck incurs in connection with this action; and

K. The Court grant such other, different, and additional relief as the Court deems just and proper.

Dated: January 3, 2008

Respectfully submitted,

Robert E. Hanlon (RH 8794)

Thomas J. Parker (TP 7219)

Alston & Bird LLP

90 Park Avenue New York, New York 10016

Tel: 212-210-9400 Fax: 212-210-9444

robert.hanlon@alston.com thomas.parker@alston.com

Attorneys for Plaintiffs Merck Eprova AG and Merck KGaA

Page 22 of 25

Exhibit A

Int. Cl.: 5

Prior U.S. Cls.: 6, 18, 44, 46, 51 and 52

Reg. No. 2,526,532

United States Patent and Trademark Office

Registered Jan. 8, 2002

TRADEMARK PRINCIPAL REGISTER

METAFOLIN

MERCK KGAA (PARTNERSHIP) FRANKFURTER STRASSE 250 64293 DARMSTADT, FED REP GERMANY

FOR: DIETARY SUPPLEMENTS, NAMELY, A DERIVATIVE OF FOLIC ACID, NAMELY, CALCIUM SALT OF L-5 METHYLTETRAHYDROFOLIC ACID, IN CLASS 5 (U S. CLS. 6, 18, 44, 46, 51 AND 52)

OWNER OF FED REP GERMANY REG. NO. 39856984, DATED 1-13-1999, EXPIRES 10-31-2008

SER NO. 75-761,680, FILED 7-27-1999.

DERRICK PHILLIPS, EXAMINING ATTORNEY

Int. Cl.: 5

Prior U.S. Cls.: 6, 18, 44, 46, 51 and 52

United States Patent and Trademark Office

Reg. No. 3,001,087 Registered Sep. 27, 2005

TRADEMARK PRINCIPAL REGISTER



MERCK KGAA (FED REP GERMANY PART-NERSHIP LIMITED BE SHARES) FRANKFURTER STRASSE 250 D-64293 DARMSTADT, FED REP GERMANY

FOR: DIETARY SUPPLEMENTS, NAMELY, A DERIVATIVE OF FOLIC ACID, NAMELY, CALCIUM SALT OF L-5 METHYLTETRAHYDROFOLIC ACID, IN CLASS 5 (U S CLS. 6, 18, 44, 46, 51 AND 52)

PRIORITY CLAIMED UNDER SEC. 44(D) ON FED REP GERMANY APPLICATION NO. 30360909 5, FILED 11-21-2003, REG. NO. 30360909, DATED 1-13-2004, EXPIRES 11-30-2013.

SER. NO 78-364,095, FILED 2-6-2004

BRIAN NEVILLE, EXAMINING ATTORNEY